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Original Article

Utilization of the ionotropic gelation technology for the development of gastroretentive floating beads of ondanesteron HCl

Sura Zuhair Mahmood[1], Iman S Jaafar[1]*, Methaq H Sabar[1], Nora Zawar Yousif[1], Muna Yehia Ismail[1]

[1]Department of Pharmaceutics, College of Pharmacy, Mustansiriyah University, Baghdad, Iraq.

Correspondence: Iman S Jaafar, Department of Pharmaceutics, College of Pharmacy, Mustansiriyah University, Baghdad, Iraq. pharm.eman.aldahan@uomustansiriyah.edu.iq

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ABSTRACT

To address the challenges posed by ondansetron's (Ond) brief biological half-life—which often limits its bioavailability and therapeutic impact—the creation of a gastroretentive controlled-release system represents a highly effective strategic approach. This research details the fabrication of ondansetron-loaded alginate floating beads synthesized via the ionotropic gelation technique. The resultant beads underwent comprehensive characterization, including assessments of drug entrapment efficiency, percentage yield, floating lag time, sustained buoyancy duration, and in vitro dissolution profiles. Furthermore, the optimal formulation was subjected to morphological analysis and an in vivo buoyancy evaluation. Data revealed that the developed beads exhibited a drug content ranging from 91.6 ± 1.2% to 98 ± 1.1% and a process yield between 85% and 97.8%. The delivery system demonstrated a floating lag time of 2–30 minutes, sustained in vitro buoyancy exceeding 24 hours, and cumulative drug release profiles spanning 75% ± 0.3% to 100% ± 0.36%. Additionally, F2, which consists of 1% Na alg, 0.5% HPMCK4M, 1% $CaCO_3$, and 2% $CaCl_2$, was selected as an optimum formula with an *in vivo* buoyant time of > 6 hrs. In conclusion, Ond alginate-based beads could be considered as promising strategy to decrease dosing frequency, improve the pharmacological activity, and enhance patient compliance.

Keywords: Buoyancy, Gastroretentive, Floating beads, Ondansetron HCl

Introduction

Despite ongoing advancements in drug delivery technology, the oral route remains the preferred method of administration, primarily due to its versatility, simplicity, and superior patient adherence [1]. Nevertheless, oral delivery faces significant challenges, particularly regarding medications that exhibit short biological half-lives. Rapid systemic elimination of such compounds following gastrointestinal absorption often compromises their overall bioavailability. To maintain therapeutic drug levels and ensure consistent pharmacological efficacy, it is frequently necessary to implement controlled-release oral systems that facilitate predictable and sustained drug delivery [2, 3].

Recent advancements in pharmaceutical technology have prioritized the development of oral delivery platforms, most notably gastroretentive drug delivery systems (GRDDS). By prolonging the gastric residence time of therapeutic agents, GRDDS facilitates controlled and/or sustained release. This mechanism enhances drug concentration at the target site, improves overall bioavailability, and allows for a reduction in required dosing frequency [4]. This unique characteristic of GRDDS enables the resolution of many problems, such as active

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ingredients with short half-lives, narrow window absorption, drug instability, low solubility in high intestinal pH, and drugs for local activity in the stomach [5]. Numerous technologies have progressed, providing different strategies to enhance drug retention in the gastric region for a longer period, for example, swellable, mucoadhesive, nanofibrous, high-density, expandable, magnetic, and floatable systems [6].

First introduced by Davis in 1968, floating or low-density gastroretentive drug delivery systems (GRDDS) represent the most extensively researched category in the field. The fundamental principle of these systems relies on possessing a bulk density lower than that of gastric fluid, which facilitates prolonged retention within the stomach and allows for the sustained, controlled release of the active pharmaceutical ingredient. These systems are broadly classified into effervescent and non-effervescent types based on their buoyant mechanism [7]. Effervescent variants incorporate carbonate components that generate carbon dioxide in situ, thereby lowering the system's overall density. In contrast, non-effervescent systems utilize hydrocolloid matrices, such as swellable or gel-forming polymers, which increase in volume upon exposure to the acidic gastric environment to achieve the necessary buoyancy [8, 9].

Alginate beads are one of the subdivisions of non-effervescent floating systems that consist of sodium alginate (interlocking agents) and hydrocolloid gel-forming agents [10]. Sodium alginate ($NaC_6H_7O_6$) is a linear biopolymer that is well-known for the development of hydrophilic matrix systems. It can form a strong thermostable gel by exchanging sodium ions with divalent cations (for instance, Ca^{+2} and Ba^{+2}) [11, 12]. Unlike other hydrophilic polymers that are commonly used, alginate can swell upon exposure to gastric pH post-gelling, enabling a sustained release of the drug; thus, it is highly recommended for GRDDS. Additionally, it provides a flexible beads manufacturing process due to the ion gelatinization of alginate course [13].

Ondansetron hydrochloride (Ond) functions as a selective antagonist of the 5-HT3 serotonin receptor. It is widely recognized as the primary pharmacological intervention for the management of chemotherapy- and radiation-induced nausea and vomiting [14-23]. Furthermore, the agent is utilized to prevent occurrences of post-operative nausea and emesis [24]. Following oral administration, Ondansetron is quickly assimilated within the gastrointestinal tract; however, its absolute bioavailability is limited to roughly 60% due to the effects of first-pass hepatic metabolism [25]. The elimination half-life of Ond after an intravenous or an oral dose is approximately 5.5 hrs on average [26]. This short half-life reduces Ond's therapeutic activity as a consequence of decreased bioavailability and requires multiple doses to provide the required effect. The objective of this research is to engineer and assess a novel sustained-release vector for Ondansetron. By prolonging drug delivery, this approach seeks to decrease dosing frequency, optimize pharmacological efficacy, and bolster patient adherence to treatment regimens.

Materials and Methods

Preparation of ond microbeads

Ond-loaded microbeads were fabricated utilizing the ionotropic gelation method. Detailed formulations are presented in **Table 1**. To initiate the process, precise quantities of sodium alginate (Na Alg), hypromellose (HPMC), and the active pharmaceutical ingredient (Ond) were incorporated into a determined volume of deionized water. This mixture was subjected to constant agitation at a speed of 50 rpm and maintained under stirring until a homogenous, clear solution was achieved. At this point, an accurate amount of $CaCO_3$ was added and mixed thoroughly till a uniform distribution with complete dissolution was achieved.

For the second beaker, a precise quantity of $CaCl_2$ was dissolved in distilled water. Subsequently, the sodium alginate drug mucilage was introduced into the solution via dropwise addition, employing a 10 mL syringe equipped with a 20-gauge needle held at a height of 5 cm. During this process, the beaker was positioned on a magnetic stirrer set to a constant agitation speed of 400 rpm. The obtained microspheres were then collected, washed with DW, dried, and stored in a tightly closed container for evaluation studies [27].

Table 1. Composition of prepared Alginate microbeads

Formula Code	Ond % w/v	Na Alg % w/v	HPMCK4M % w/v	HPMCK100 LV % w/v	$CaCO_3$ % w/v	$CaCl_2$ % w/v
F1	0.1	0.5	0.5		1	2
F2	0.1	1	0.5		1	2
F3	0.1	2	0.5		1	2
F4	0.1	2			1	2
F5	0.1	2	1		1	2
F6	0.1	2	1.5		1	2
F7	0.1	2		1	1	2
F8	0.1	2	0.5	0.5	1	2

Drug content determination

To determine the drug loading, a precise quantity of Ond-loaded microbeads—calculated to contain 10 mg of the active pharmaceutical ingredient—was pulverized using a mortar and pestle. The resulting powder was dispersed into 30 mL of 0.1 M HCl (pH 1.2) and subjected to continuous agitation for 60 minutes to ensure complete extraction. Subsequently, the mixture was passed through a 0.45 µm syringe filter, and the concentration of the filtrate was quantified via UV-spectrophotometry at a wavelength of 310 nm [28]:

Percentage yield

The percentage yield for each Ond-alginate bead formulation was determined by calculating the ratio of the recovered bead weight to the theoretical weight of the initial raw materials, as defined by the following equation [29]:

$$yeild\ \% = \frac{\text{Actual weight of } formulated \text{ beads}}{Theoretical\ weight\ of\ formulated\ beads} * 100 \quad (1)$$

Floating time study

To evaluate the buoyancy behavior of the formulations, a USP type II dissolution apparatus (paddle method, Copley, UK) was employed. The testing medium consisted of 900 mL of 0.1 N HCl, kept at a controlled temperature of 37 °C ± 0.5 °C, with the paddle speed fixed at 50 rpm. The "floating lag time" was defined as the interval required for the immersed beads to ascend to the surface of the medium. Simultaneously, the "total floating time" was measured as the period during which the beads remained continuously buoyant on the surface. These two parameters collectively define the in vitro buoyancy profile of the tablets [30].

In vitro drug release study

To assess the release kinetics of the floating Ond beads, a USP type II dissolution apparatus was employed. The test was conducted by placing a sample containing 40 mg of Ond into 900 mL of pH 1.2 HCl solution, maintained at a constant temperature of 37 ± 0.5 °C and stirred at 50 rpm. Throughout the duration of the study, 5 mL samples were periodically withdrawn and replaced with fresh dissolution media to preserve sink conditions. The quantity of Ond liberated into the medium was measured spectrophotometrically at 310 nm [31].

Selection of the optimum formula

The ideal formulation was determined based on a comparative assessment of key parameters, including % yield, drug loading, floating behavior, and release kinetics; this selected formulation was then subjected to further analytical characterization.

Field emission scanning electron microscopy (FESEM)

To evaluate the surface morphology of the optimized Ond-loaded microbeads, high-resolution imaging was conducted using a field emission scanning electron microscope (Inspect F50, FEI, Netherlands). The analysis was performed at an accelerating voltage of 30 kV [32].

In vivo buoyant study

To validate the buoyancy characteristics of the formulated Ond-loaded microbeads, an *in vivo* study was conducted using ultrasonography in a rat model. This research protocol received formal approval from the Animal Ethical Committee at the College of Pharmacy, Mustansiriyah University.

For this research, three healthy young albino rats were utilized as subjects. The animals were individually housed within a controlled laboratory environment maintained at a constant temperature of 25±2°C [33-38]. The optimized formula was administered to the rats that were fasted for 12 hours and given only free access to water to guarantee consistent gastrointestinal motility. By keeping the prerequisite conditions of ultrasonography, the whole rat abdomen was observed, and the ultrasonography images were collected at 30 min and 6 hr [39].

Statistical analysis

All experimental data were processed using IBM SPSS Statistics 25. Statistical significance was determined via analysis of variance (ANOVA), with findings considered significant at a threshold of $p < 0.05$ [40].

Results and Discussion

Drug content

Drug content assessment was accomplished to estimate the amount of Ond in the formulated beads to assure uniform distribution; the obtained results stated that it is in the range of 91.6+ 1.2 to 98 +1.1% as shown in **Table 2**, which aligns with the acceptable limits according to USP, indicating the reproducibility of the employed method of preparation [41].

Table 2. Drug content, yield percentage, and floating behavior of Ond-loaded beads

Formula Code	Content %	Yield %	Floating lag time (min)	Floating duration (hrs)
F1	91.6+ 1.2	85	2	>24
F2	94+1.6	92	5	>24
F3	96.3+1.5	94	15	>24
F4	97.1+1.3	97.2	30	>24
F5	98+1.1	97.8	25	>24
F6	97.5+1.6	97	20	>24
F7	94.8+1.2	87	20	>24
F8	96.5+1.3	95	27	>24

Percentage yield

The practical yield for the synthesized alginate beads (F1 to F8) was determined, with the findings presented in **Table 2**

indicating a recovery range of 85% to 97.8%. A yield less than 100% could be attributed to the material loss during the bead formulation process and during the filtration process [42]. A positive correlation was identified between the sodium alginate (Na alg) concentration and the percentage yield, as evidenced by the results for formulations F1 through F3, which achieved yields of 85%, 92%, and 94%, respectively. This trend can be attributed to the dynamics of the cross-linking process: at lower Na alg concentrations, the polymer chains on the droplet periphery undergo rapid cross-linking upon contact with the calcium chloride ($CaCl_2$) solution. This immediate solidification creates a barrier that restricts the inward diffusion of calcium ions, leaving the core polymer chains un-crosslinked. Conversely, increasing the polymer concentration slows the initial surface cross-linking rate, thereby facilitating deeper calcium ion penetration into the droplet and promoting more extensive cross-linking throughout the internal matrix [43]. A similar observation was obtained in the development of calcium-alginate beads of apigenin [44].

Floating behavior study

The buoyancy performance of the synthesized alginate beads was evaluated in a 0.1 N HCl medium (pH 1.2). Experimental findings indicated that the formulations achieved a floating lag time (FLT) ranging from 2 to 30 minutes, with a total floating duration extending to 24 hours. A statistically significant correlation ($p < 0.05$) was observed between sodium alginate (Na Alg) concentration and FLT; specifically, formulations F1, F2, and F3 exhibited lag times of 2, 8, and 15 minutes, respectively. This trend suggests that higher alginate concentrations increase the viscosity of the precursor solution, thereby hindering the escape of CO_2 bubbles and retarding initial buoyancy. Furthermore, higher polymer concentrations appear to promote the formation of a less porous, more compact matrix, which limits the number and distribution of pores necessary for effective flotation. This densification is further exacerbated by the internal ionotropic gelation induced by $CaCO_3$, which creates a more robust cross-linked network and subsequently reduces overall buoyancy [45]. These results are consistent with those previously reported by Ibrahim *et al.* [46].

In vitro drug release study

To simulate the gastric environment in vivo, release studies of Ondansetron (Ond) loaded within various alginate bead formulations were performed in 0.1 N HCl (pH 1.2).

As illustrated in **Figures 1 and 2**, the incorporation of the drug into an alginate bead matrix significantly slowed its release profile [47]. This phenomenon can be attributed to the complex, multi-stage mechanism governing drug release from alginate-based systems. Specifically, the process requires the initial penetration of the dissolution medium into the bead core, followed by polymer swelling, the subsequent erosion of the alginate network, and the eventual diffusion of the dissolved drug through the hydrated matrix. Due to this tortuous path, the drug molecules must traverse a considerable distance before reaching the bead surface, thereby prolonging the overall dissolution duration [43]. These findings are consistent with previous observations documented by Mandal *et al.* [48]. The obtained results also demonstrated an initial burst release in all formulations, which could be justified by the presence of untrapped or surface-adsorbed drug, as well as the wide pores provided by alginate beads [48]. Additionally, the solubility of Ond is potentiated by acidic pH due to its basic nature [49]. A similar observation was reported in the development of floating beads of domperidone [50].

As depicted in **Figure 1**, the data indicate that elevating the Na alg concentration led to a negligible decrease in Ond release ($p > 0.05$). Specifically, formulations F1, F2, and F3, which maintained a constant HPMCK4M level of 0.5% while incorporating 0.5%, 1%, and 1.5% Na Alg, respectively, exhibited drug release rates of 93%, 91%, and 89% over a 6-hour period. This trend is attributable to the higher density of cross-linking sites formed by the interaction of glucuronic acid residues at greater Na alg concentrations. These reinforced structural junctions effectively sequester a larger proportion of the drug, thereby impeding its release [51]. These observations are consistent with previously reported findings by Rasel *et al.* [52].

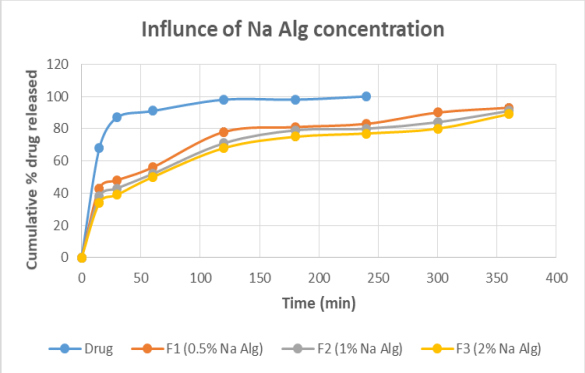


Figure 1. Influence of Na Alg concentration on Ond release

Figure 2 demonstrates that drug release is inversely proportional to the concentration of HPMCK4M when sodium alginate is held constant at 2%. Increasing HPMCK4M levels from 0% to 1.5% significantly inhibited drug delivery ($p < 0.05$), with 6-hour release values dropping from 95% in formulation F4 to 75% in formulation F6. The reduced drug release rate in the presence of HPMCK4M can be justified by the reduction of the pore formation in the presence of HPMCK4M, since it can develop a viscous microenvironment upon hydration with dissolution medium, which increases upon increasing the polymer concentration, with a preceding reduction in drug release rate [53]. Connected findings were obtained in the ambroxol hydrochloride alginate beads formulation [54].

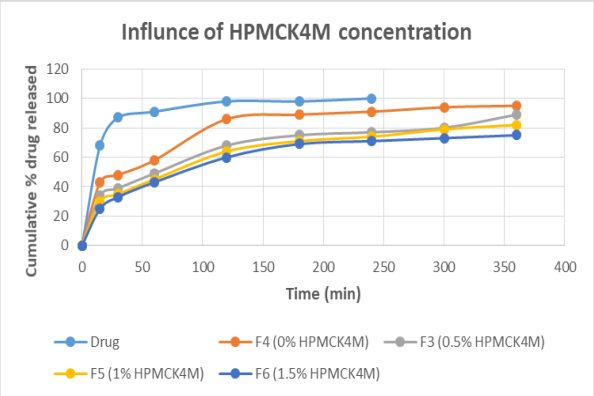


Figure 2. Influence of HPMCK4M concentration on Ond release

As illustrated in **Figure 3**, replacing HPMCK4M (F3) with an equal concentration (0.5%) of HPMCK100 LV (F7) resulted in a statistically significant enhancement in drug release ($p < 0.05$). This outcome is primarily attributed to variations in the viscosity of the matrix when exposed to the dissolution medium. Specifically, the higher-viscosity HPMCK4M grade facilitates the formation of a more robust gel layer, which hinders drug diffusion through increased polymer chain entanglement and enhanced swelling resistance [55]. This finding aligns with the results reported by Alwan *et al*. [40].

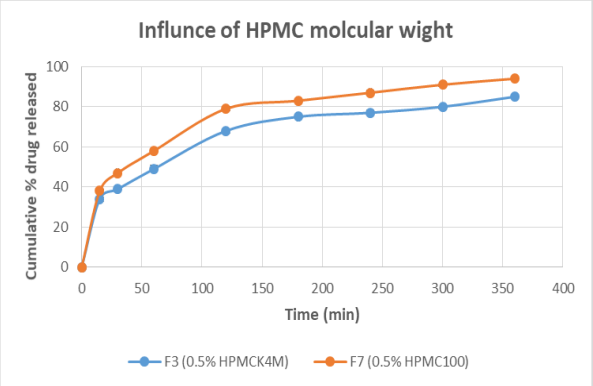
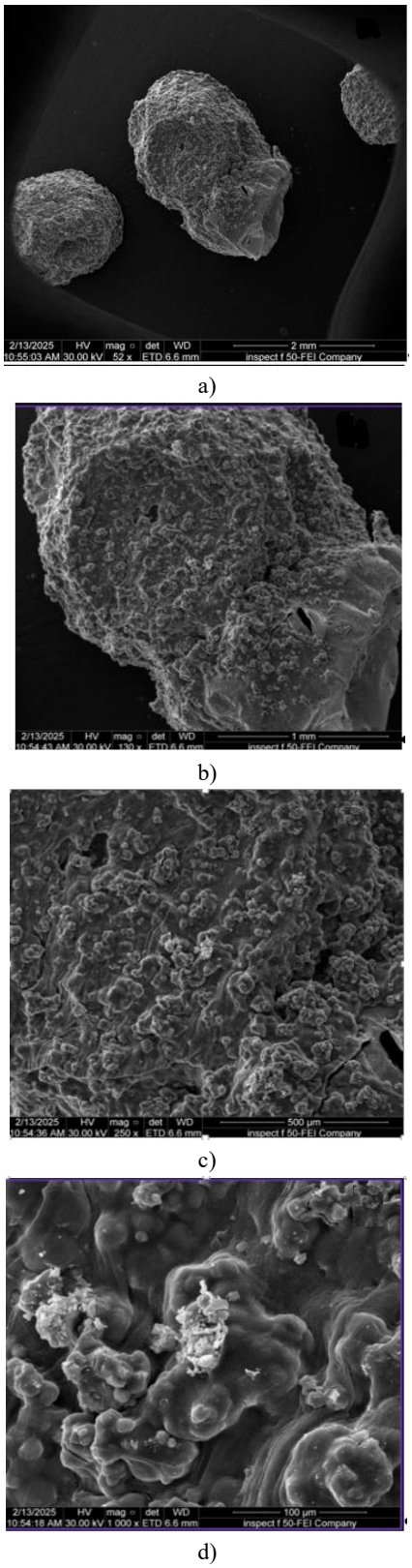


Figure 3. Influence of HPMCK4M molecular weight on Ond release

Field emission scanning electron microscopy (FESEM)

Field-emission scanning electron microscopy (FE-SEM) was employed to characterize the topographical features of the synthesized alginate beads. As illustrated in **Figures 4a and 4b**, the beads displayed a largely irregular spherical geometry characterized by a textured, porous exterior. Upon further magnification (×250 and ×1000, **Figures 4c and 4d**), the surface appeared to be embedded with crystalline solids, potentially representing either drug molecules and/or calcium carbonate deposits. This phenomenon is likely attributed to the migration of these particles toward the bead surface alongside water during the dehydration phase [46]. These observations are consistent with previous findings reported by Manjanna *et al*. [56].



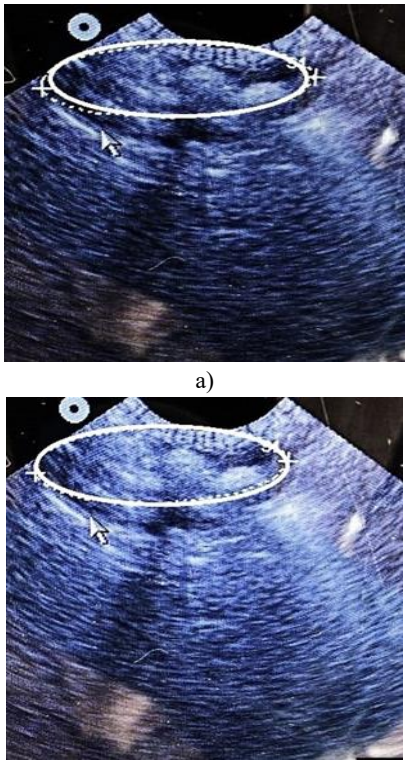
a) b) c) d)

Figure 4. FESEM photographs of surface morphologies of optimum formula

In vivo buoyant study

The optimum Ond-loaded beads were nominated for the assessment of *in vivo* floating competence by ultrasonographical technique. The obtained graphs at 30 min and 6 hrs are shown in **Figures 5a and b**, which align with the results obtained for the

in vitro floating study and designate even distribution of the formula over the gastric fluid and floats for more than 6 h.



a)

b)

Figure 5. Ultrasonography images of formulation in the gastric region of rat: (a) 30 min after dosing, and (b) 6 hr after dosing.

Conclusion

Utilizing the ionotropic gelation technique, Ond-loaded floating beads were prepared with high reproducibility. The study established that Na-alginate concentration directly influences the percentage yield and floating lag phase. Moreover, the drug release kinetics were inversely related to the polymer's molecular weight and concentration, demonstrating that these parameters effectively mitigate drug leakage from the bead matrix. Additionally, it was concluded that F2, which provides an optimum floating lag time (4 min), acceptable cumulative drug release (93% within 6 hrs), optimum floating lag time (4 min), and an *in vitro* and *in vivo* buoyant time (> 24 hrs and 6 hrs, respectively) is the selected optimum formula. Lastly, the Ond-loaded beads demonstrate significant potential as an oral delivery vehicle. By facilitating a controlled release profile for up to six hours, this system likely improves both drug absorption and bioavailability. Consequently, this formulation could enhance patient adherence by minimizing the required dosing frequency.

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Conflict of interest: None

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Ethics statement: None

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